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14. ABSTRACT: The hypothesis to be tested is that there are allelic variations of some genes that make the development of diabetes-related complications more likely in patients who carry them than those who do not. The 3 major complications to be evaluated are diabetic nephropathy, diabetic neuropathy, and diabetic retinopathy. This is an observational study in which the investigators will obtain DNA samples from the blood of patients with one or more of these complications and from as many their first-degree relatives as possible for testing in the laboratory of Dr. Massimo Trucco is an internationally known immunologist and respected leader in genetic research in diabetes. He will evaluate these samples by studying candidate genes selected a priori and testing for transmission/disequilibrium – a standard for analysis of linkage between a candidate gene and a specific disease.					
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Introduction

Although deaths today from the acute effects of diabetes are rare, the associated vascular, retinal, neurological and renal complications are responsible for high levels of morbidity and mortality in diabetes. It has been observed that only a subset of diabetics appear to be susceptible to the development of diabetic complications, i.e., nephropathy, autonomic neuropathy, and retinopathy and there is data to suggest that there is a genetic component to this increased susceptibility. The proposed investigation will test that hypothesis that there are allelic variations of some genes that make the development of diabetes-related complications more likely in patients who carry them than in those who do not. Initial emphasis will be examining candidate gene analysis in families for diabetic nephropathy, autonomic neuropathy, and retinopathy.

Body

The title of this study is "Genetic Screening in Diabetes." This is an observational study in which COL Vigersky and his research team will obtain DNA samples from the blood of patients at least one of three diabetic complications (as specified in SF298) and from as many of their first-degree relatives as possible for genetic testing. The study will be performed at WRAMC for DEERS-eligible subjects and at the Uniformed Services University of Health Sciences (USUHS) for non-DEERS-eligible subjects. After meeting eligibility requirements, all subjects will complete a medical history, a quality of life questionnaire, a physical examination, blood and urine sampling and analysis, and additional procedures to rule out diabetes and the presence or absence of the three diabetes-related complications that are being studied. All blood samples will be typed and examined to evaluate if there are reasonable candidate genes that contribute to the genetic susceptibility and/or development of diabetic nephropathy, neuropathy, and retinopathy. It is expected that WRAMC will enroll up to 100 probands and 300 of their family members.

Key Research Accomplishments

After extensive revisions, the study was approved by the Clinical Investigation and Human Use Committees at WRAMC in March 2006 and the Clinical Investigation Research Office in April 2006. The protocol is currently undergoing review by the Institutional Review Board (IRB) at USUHS where the studies on non-DEERS eligible relatives will take place. Recruitment will begin when the protocol has been approved by the USUHS IRB.

Reportable Outcomes

Funding in the amount of \$132,000.00 has been requested to cover the costs associated with personnel and consumable supplies for this study under a Cooperative Research and Development Agreement between the T.R.U.E. Research Foundation and the Clinical Regulatory Office.

Conclusions

Not Applicable.

References

None.

Appendices

None.

Supporting Data

Not Applicable.